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foam only with propellant!
claims ohne propellant.
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(54) FOAMABLE BIOCIDE COMPOUNDS.

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Description

The present invention relates to a foamable biocidal composition.

The chemical control of bacteria and viruses is assuming increasing importance in the hospital and medical environment. Outbreaks of infections such as Methyicylin resistant Staph Aureus are causing illness, death and even temporary closure of wards in some hospitals.

This situation has been exacerbated by the failure of many bacteria to respond to conventional antibiotics. Accordingly, the need for effective control of bacterial and virus organisms is assuming greatly increased significance.

In the case of hand and skin disinfection a biocidal agent needs to kill the widest possible range of microorganisms in the least possible time without toxicity, irritation or other hazard and have a long shelf life.

Typical of these biocides are chlorine, iodophors and organic chemicals such as chlorhexidine which are commonly employed in hospitals and surgeries. The most widely accepted form of safe, effective biocide is chlorhexidine gluconate in aqueous ethanol. A full discussion of this product appears in the paper entitled "Detergents compared with each other and with antiseptics as skin 'degerminating agents'" by H.A. Lily et al in Journal of Hygiene (U.K.). Further technical disclosure of the product appears in Australian Patents Nos. 157,758 and 222,033. Conventionally, chlorhexidine is commercially supplied in a pump pack or manufactured by the hospital pharmacist as required.

Unfortunately, however, in use alcoholic chlorhexidine has inherent difficulties including the following:

(1) Openable bottles of alcoholic chlorhexidine are subject to contamination both at the time of fitting the pump head and when the pump is being operated.

(2) The 60-70% aqueous ethanol system is highly flammable. Spillage from the plastic bottle or dispenser at any time could result in a fire.

(3) The mist as applied from pump dispensers is a highly flammable mist. This could be highly dangerous since it is being sprayed directly onto the skin.

(4) The spray mist does not confine itself to the target area, wastage occurs due to overspray.

(5) The alcoholic lotion as sprayed on the skin is difficult to control due to its low viscosity. It tends to run off the skin and evaporate rapidly before being evenly distributed.

(6) The shelf life of pump packs of a volatile fluid such as alcohol is restricted by the fact that they do not seal the pack perfectly and evaporation can occur over a period of time.

(7) The spray or lotion product is messy to use since once one hand has been sprayed it must become contaminated as the pack is held to spray the other hand.

US-T-943 010 relates to a primarily aqueous foamable chlorohexidine composition, of limited biocidal activity, containing corrosive ethoxylated surfactants.

Accordingly, it is well known that chlorhexidine must be formulated very carefully to optimize its biocidal performance.

DESCRIPTION OF THE INVENTION

With the above difficulties in mind, the present invention provides an improved composition containing alcoholic chlorhexidine in aerosol form which is easy and safe to use. In this respect, extensive research over several years was necessary on a variety of differing types compositions before the viability of an aerosol type became apparent.

Accordingly, a biocidal composition, comprising:

(a) 0.1 to 10% w/w of chlorhexidine;
(b) 40 to 90% w/w aliphatic alcohol;
(c) up to 40% w/w water;
(d) 0.5 to 10% w/w fatty alcohol;
(e) 0.1 to 15% w/w surface active agent;
(f) 3 to 30% w/w propellant

The inclusion of a corrosion inhibitor is necessary where the composition is stored in metal containers which are typical of tin plate or aluminum to counteract the corrosive nature of chlorhexidine formulations. However, if the container is non metal e.g. glass the inclusion of a corrosion inhibitor is not necessary.

As stated the composition of the invention is an aerosol form. This is most appropriate for a biocide as it avoids or minimizes the conventional defects of contamination and spillage. Pressurized aerosol containers are readily available, have been extensively tested and are well accepted.

PREFERRED FEATURES OF THE INVENTION

In an effort to minimize the aforementioned difficulty of overspray and early evaporation, a foaming agent was included, more particularly of a quick break foam variety. This has the ability of providing a thick ball of foam which disintegrates easily when spread. Proper coverage can be effected to the surface to be cleansed without premature evaporation. A general discussion of quick break foams can be found in Australian Patent 463,216. In a preferred embodiment of the present invention, a particular quick break foaming agent has been developed which has not been previously disclosed in this context.

From the viewpoint of performance it was known from the paper of H.A. Lilly et al that aqueous ethanol of approximately 70% w/w ethanol concentration is the best vehicle for chlorhexidine and this is the preferred form for use in the present composition.

It is also well known that a base formulation of chlorhexidine in aqueous ethanol tends to degrease and dry out the skin when used regularly (e.g. 40 times per shift) in the hospital environment. Thus, an emollient is optionally incorporated which would help prevent dehydration of the skin without hindering the performance of chlorhexidine. Emollients which are particularly preferred are lanolin and polyols selected from glycerol, propylene glyerol, sorbitol and low molecular weight polymers thereof. Other examples of emollients are vinyls alcohol and polyvinyl pyrrolidone.

When considering the preferred requirement for 70% w/w ethanol, it was found that the composition may have an effect on the solubility characteristics of other additive e.g. fatty alcohols, lanolin and organic acid salts. It is believed the other additives react with the chlorhexidine causing it to be, to some extent, either precipitated or inactivated. Nevertheless, such compositions are still found to be useful.

The chlorhexidine component will normally be present in amounts of from .1-10% w/w though larger concentrations were found to be possible but with deleterious effects on the efficiency of entire system. Preferred forms of chlorhexidine are as a gluconate, diacetate, hydrochloride or other salts thereof.

Care should be taken to select a propellant most compatable to the entire system and in this respect the propellant is preferably selected from a group comprising propane, butane, dichloro difluoro methane, dichloro tetra fluoro ethane, octafluoro cyclo butane. As mentioned the propellant should be presenting amounts from 3 - 30% w/w though preferably from 5 to 15% w/w and more preferabely from 8 to 10% w/w.

Where the container is metal it is necessary to incorporate a corrosion inhibitor. This became apparent when researching the invention as several working formulation were achieved which however were found to corrode tin plate or aluminium containers at extraordinary rates resulting in short shelf lives. Typical corrosions inhibitors were organic acid salts more preferably sorbic acid, benzoic acid, sodium benzoate and potassium sorbate.

These inhibitors are preferably present in amounts of from .1 to 15% wt and more preferably for .1 to 3% w/w.

Thus, a typical formulation of the present invention is as follows:

	% w/w
Propellant (e.g. propane, butane, dichloro difluoro methane, dichloro tetra fluoro ethane, octafluoro cyclo butane and mixtures thereof)	3 - 30
Chlorhexidine (as gluconate, diacetate hydrochloride and mixtures thereof, & other salts)	.1 - 10
Fatty alcohol (e.g. cetyl, stearyl, lauryl, myristyl, palmityl and mixtures thereof)	.5 - 10
Aliphatic alcohol (e.g. methyl, ethyl, isopropyl, butyl and mixtures thereof)	40 - 90
Water	10 - 40
Polyol (e.g. glycerol, propylene glycol, sorbitol & low molecular weight polymers thereof)	1 - 10
Organic acid salt (e.g. sorbic acid, benzoic acid)	.1 - 15
Surface active agent (e.g. ethyoxylated sorbitan stearate, palmitate, oleate, nonyl phenol ethoxylates, fatty alcohol ethoxylates)	.1 - 15

Chlorhexidine diacetate	1.0
Myristyl alcohol	3.0
Ethoxylated cetylalcohol	0.8
Clycerol	2.5
Isopropyl alcohol	60.0
Potassium sorbate	0.3
Purified water	25.4
Butane/propane	7.0
	100.0

The following are details of tests which were carried out of such formulations in which the formulation is identified by the Trade mark HEXIFOAM®.

TEST A

A series of In-vitro tests were performed on "Hexifoam®" to determine the efficacy of the Chlorhexidine within this formulation.

The tests were designed to establish whether any loss of biocidal activity of the chlorhexidine was occurring. Comparative evaluations were also performed utilizing "Hexifoam®" (without Chlorhexidine) and unformulated non-alcohol Chlorhexidine Gluconate Standard.

The product was evaluated in a suspension test based on the principles outlined in BS.3286 under the following test conditions.

Product Dilutions:	1:2 v/v, 1:4 v/v
Contact Time;	1 minute, 2 minutes, 3 minutes 5 minutes
Organism:	Pseudomonas aeruginosa NCTC 6749
Organic Challenge:	10% Sheep Serum
Inoculum Density:	106 - 107 orgs/ml
Product Diluent:	Distilled Water with 10% Sheep Serum
Inactivator:	Nutrient Broth N.2, Lecithin, Tween® 80
Temperature:	Ambient

Results

Sample	Dilution/ Concentration	Initial Count per ml	Surviving Organisms per ml 1min	2min	3min	5min
Hexifoam®	1:2	8.0×10^6	10	10	10	10
Hexifoam® without Chlorhexidine	1:2	8.0×10^6	10	10	10	10

			1 min	2 min	3 min
Hexifoam®	1:4[1]	3.9×10^6	10	10	10
Hexifoam® without Chlorhexidine	1:4	3.9×10^6	1,500,000	800,000	500,000
Chlorhexidine Gluconate	0.25%	5.0×10^6	10	10	10

Notes

1 At 1:4 dilution of Hexifoam® the concentration of Chlorhexidine is 0.25%.

2 ' / ' indicates less than
Less than 10 is the detection sensitivity of the test method i.e. no surviving organisms detected.

Conclusion

The results have indicated that a dilution of the product Hexifoam® of 1:4 v/v continues to demonstrate excellent biocidal properties while the base material without chlorhexidine fails to show any significant biocidal properties. This is indicative of little or no loss of activity of the chlorhexidine within the formulation.

The comparative tests with Chlorhexidine Gluconate standard at 0.25% confirmed that the biocidal activity under the above test conditions was found to be equivalent.

The product Hexifoam® has shown very rapid biocidal action against the organisms Pseudomonas aeruginosa and Staphylococcus aureus (Our Ref N 17,614). Complete kill of the test organisms was achieved within 1 minute in the in-vitro tests performed to date.

TEST B

A sample of "Hexifoam®" was received at the laboratory to be evaluated for its biocidal properties against the organism Staphylococcus aureus.

The product was evaluated in a suspension test in ccordance with the principles outlined in BS. 3286 under the following test conditions.

Product Dilution:	1:2 v/v
Contact Time:	1 minute, 2 minutes, 5 minutes
Organism:	Staphylococcus aureus 4163
Organic Challenge:	10% Sheep Serum
Inoculum Density:	10^6 orgs/ml,
Product Diluent:	Standard Hard Water - 10% Sheep Serum
Inactivator:	Nutrient Broth No. 2 Lecithin Tween® 80
Temperature:	Ambient

Initial count	Final Count per ml *		
	1 min	2 min	5 min
2.0×10^6	Less than 10	Less than 10	Less than 10

The Kill Factor achieved in all cases was greater than 2.0×10^5

* Results presented are Geometric Means of duplicate tests.

TEST C

The product Heixfoam® batch 4073 was evaluated for its biocidal activity using a suspension test based on the principles outlined in British Standard BS.3286. The results obtained are as follows:-

Product:	Hexifoam®
Test Organism:	C.albicans ATCC 10231
Product Dilution:	1:2 w/v
Diluent:	Distilled water with 10% sheep serum
Organic Challenge:	10% sheep serum
Temperature:	Ambient
Contact Time:	One Minute
Inactivator:	Nitrient Broth No. 2 (Oxoid) with lecithin and Tween® 80.

Initial Count	Final Count	Kill Factor	% Kill
3.7×10^6	Less than 10	Greater than 3.7×105	Greater than 99.99973

Notes

1. Results presented are geometric means of duplicate results.
2. Kill factor is defined as the ratio of initial count versus final count.
3. A kill factor of 10^4 is regarded as significant biocidal activity.

TEST D

The product Hexifoam® batch 4073 was evaluated for its biocidal activity using a suspension test based on the principales outlined in British Standard BS.3286. The results obtained are as follows:-

Product:	Hexifoam®
Test Organism:	E.coli NCTC 8196
Product Dilution:	1:2 w/v
Diluent:	Distilled water with 10% Sheep serum
Organic challenge:	10% Sheep serum
Temperature:	Ambient
Contact Time:	One minute
Inactivator:	Nutrient broth No. 2 (Oxoid) with lecithin and Tween® 80.

Initial Count orgs/ml	Final Count orgs/ml	Kill Factor	% Kill
6.7×10^6	Less than 10	Greater than 6.7×10^5	Greater than 99.99986

Notes:

1. Results presented are geometric means of duplicate results.
2. Kill factor is defined as the ratio of initial count versus final count.
3. A kill factor of 10^4 is regarded as significant biocidal activity.

TEST E

The product Hexifoam® batch 4073 was evaluated for its biocidal activity using a suspension test based on the principles outlined in British Standard BS.3286. The results obtained are as follows:-

Product:	Hexifoam®
Test Organism:	S.typhimurium (clinical isolate)
Product Dilution:	1:2 w/v
Diluent:	Distilled water with 10% sheep serum
Organic Challenge:	10% sheep serum
Temperature:	Ambient
Contact Time:	One Minute
Inactivator:	Nutrient broth No. 2 (Oxoid) with lecithin and ween® 80.

Initial Count Orgs/ml	Final Count Orgs/ml	Kill Factor	% Kill
6.7×10^6	Less than 10	Greater than 6.7×10^5	Greater than 99.99986

Notes

1. Results presented are geometric means of duplicate results.
2. Kill factor as defined as the ratio of initial count versus final count.
3. A kill factor of 10^4 is regarded as significant biocidal activity.

TEST F

The product Hexifoam® Batch 4073 was evaluated for its biocidal activity using a suspension test based on the principles outlined in British Standard BS.3286. The results obtained are as follows:-

Product:	Hexifoam
Test Organism:	S.aureus (Methicillan Resistant, Clinical Isolate)
Product Dilution:	1:2 w/v
Diluent:	Sterile Distilled Water with 10% Sheep Serum.
Temperature:	Ambient
Contact Time:	One Minute
Inactivator:	Nutrient Broth No.2 (Oxoid) with Lecithin and Tween® 80.

Initial Count (Orgs/ml)	Final Count	Kill Factor	% Kill
4.6×10^6	Less than 10	Greater than 4.6×10^5	Greater than 99.9954%

Notes:

1. Results presented are geometric means of duplicate results.
2. Kill factor is defined as the ratio of initial count versus final count.
3. A Kill Factor of 10^4 is regarded as significant biocidal activity.

TEST G

The product Hexifoam® Batch 4073 was evaluated for its biocidal activity using a suspension test based on the principles outlined in British Standard BS.3286. The results obtained are as follows:-

Product:	Hexifoam®
Test Organism:	T.rubrum (clinical isolate)
Product Dilution:	1:2 w/v
Diluent:	Distilled Water with 10% Sheep Serum
Organic Challenge:	10% Sheep Serum
Temperature:	Ambient
Contact Time:	5 minutes
Inactivator:	Nutrient Broth No.2 (Oxoid) with lecithin and Tween® 80

Initial Count Orgs/ml	Final Count Orgs/ml	Kill Factor	% Kill
1.0×10^7	Less than 10	Greater than 1.0×10^6	Greater than 99.9999

Notes

1. Results presented are geometric means of duplicate results.
2. Kill factor is defined as the ratio of initial count versus final count.

TEST H

Hexifoam® was evaluated in our laboratory in a short, preliminary in-vivo trial using various dosages and exposure times against Pseudomonas aeruginosa NCTC 6749. Experimental Design

Two volunteers from our laboratory were used. For the duration of the experiment the hands of the personnel were allowed to be washed only with traditional bar soap. No chlorhexidine based products such

as our standard laboratory scrub were used to ensure there was no build up of chlorhexidine on the skin. The time interval between Hexifoam® trials was at least three days.

Fresh 24 hour suspension cultures of P.aeruginosa NCTC 6749 were utilised for each trial. Cultures were grown in Wright and Mundy broth (Difco) for 24 hours at 37°C.

One ml. of P.aeruginosa representing at least 1 x 10^9 cells was applied to the palm of one hand. This was then carefully rubbed over the surface of both hands. No culture was allowed to be dropped from the hands during this operation. If so the trial was declared void at that time, the person washed their hands and the inoculation was repeated after a break of at least two hours. The culture was allowed to dry completely on the hands before application of Hexifoam®.

Hexifoam® was weighed on to a plastic square and then applied to the hands. This procedure ensured accurate dosage by weight. The Hexifoam® was rubbed over the entire surface of the hands. Exposure time was monitored with a stop watch. At the end of the allocated exposure time the hands were placed into 500 ml. of inactivator solution comprising 3% Tween® 80, 2% lecithin. For one minute the hands were scrubbed in the inactivator solution to release any surviving P.aeruginosa into the liquid.

Trial Description	Weight of Hexifoam® Used (g)	Exposure Time (s)
Recovery Control	0	0
Test 1	1	30
Test 2	2	30
Test 3	2	60

Results

Recovery Control

Culture Count onto Hands Total Cells	Control Recovery Total Cells		% Recovery		Geometric Mean % Recov-
	Volunteer		Volunteer		
	1	2	1	2	
2.8×10^9	5.5×10^6	21.0×10^6	0.196	0.750	0.384

0.384% is used to calculate the expected recovery in all Hexifoam® trials. This adjusts for culture variation and is needed to calculate reductions achieved.

Hexifoam Trials

Trial Description	Culture Count onto Hands Total Cells (y)	Recovery Total Cells	
		Volunteer	
		1	2
1 g 30 s	3.1×10^9	1.3×10^6	3.2×10^6
2 g 30 s	2.6×10^9	5.0×10^5	5.5×10^5
2 g 60 s	4.3×10^9	2.55×10^4	11.5×10^4

Trial Description	Geometric mean Recovery	Calculated Recovery 0.384% x y	Mean Log Reduction	Kill
1 g 30 s	2.03×10^6	11.9×10^6	0.768	82.95
2 g 30 s	5.24×10^5	10.0×10^6	1.281	94.76
2 g 60 s	5.4×10^4	16.5×10^6	2.485	99.67

The foamable compositions within the present invention improve over prior chlorhexidine products commercially available as follows:-

(1) As a pressurised aerosol the pack cannot become internally contaminated.

(2) The aerosol cannot spill and therefore represents no fire hazard.

(3) The foam, as dispensed, is very hard to ignite and will not readily burn as does a spray, presenting a much reduced hazard.

(4) The foam is easily handled and does not allow any waste due to overspray.

(5) The foam as developed is of a fast breaking variety. When applied to the skin it is a stable lump, but body heat or friction cause it to melt and spread onto the skin in a unique, controllable, and fast dispersing manner.

(6) The shelf life of the aerosol is good and with some formulation is probably in excess of five years almost irrespective of the storage environment.

(7) Since a ball of foam can be held in one hand the pack only needs to be touched once and the treated hands never need to come into contact with it.

Quite unexpectedly, having regard to the prior research carried out the stated combination has in testing exceed performance expectation. Further, as disclosed initial microbiological tests have shown the compositions retain the full broad specrum of activity of chlorhexidine and to be surprisingly fast acting, killing 99% plus of M.R.S.A. in less than sixty seconds. This result is clearly superior to conventional chlorhexidine compositions.

Claims

1. A biocidal composition comprising:
   (a) 0.1 to 10% w/w of chlorhexidine;
   (b) 40 to 90% w/w aliphatic alcohol;
   (c) up to 40% w/w water;
   (d) 0.5 to 10% w/w fatty alcohol;
   (e) 0.1 to 15% w/w surface active agent;
   (f) 3 to 30% w/w propellant

2. The composition of claim 1 further includes an organic acid salt corrosion inhibitor.

3. The composition as claimed in claim 1 wherein the chlorhexidine is selected from a gluconate, diacetate or hydrochloride.

4. The composition of claim 1 wherein the aliphatic alcohol is selected from methanol, ethanol, isopropanol and butanol.

5. The composition of claim 1 wherein the fatty alcohol is selected from cetyl alcohol, stearyl alcohol, lauryl alcohol, myristyl alcohol and palmityl alcohol.

6. The composition of claim 1 wherein the ethoxylated surface active agent is selected from ethoxylated sorbitan stearate, palmitate, oleate, nonyl phenol ethoxylates and fatty alcohol ethoxylates.

7. The composition of claim 1 wherein the propellant is selected from propane, butane, dichlordifluoro methane, dichloro tetra fluoro ethane and octafluoro cyclo butane.

8. A composition as claimed in claim 2 wherein the corrosion inhibitor is present in amounts from 0.1 to 15% w/w.

9. The composition of claim 2 wherein the organic acid salt is selected from sorbic acid and benzoic acid.

10. The composition of claim 1 further including an emollient.

11. The composition of claim 11 wherein the emollient is selected from lanolin, vinyl alcohol, polyvinyl pyrollidone and polyols selected from the group consisting of glycerol, propylene glycol, and sorbitol.

Revendications

1. Une composition biocide comprenant :
   (a) 0,1 à 10 % p/p de chlorhexidine ;
   (b) 40 à 90 % p/p d'alcool aliphatique ;
   (c) jusqu'à 40 % p/p d'eau ;
   (d) 0,5 à 10 % p/p d'alcool gras ;
   (e) 0,1 à 15 % p/p d'agent tensio-actif ;
   (f) 3 à 30 % p/p de propulseur.

2. La composition de la revendication 1 comprenant de plus un sel d'acide organique inhibiteur de la corrosion.

3. La composition de la revendication 1, dans laquelle la chlorhexidine est choisie parmi un gluconate, diacétate ou chlorhydrate.

4. La composition de la revendication 1, dans laquelle l'alcool aliphatique est choisi parmi le méthanol, l'éthanol, l'isopropanol et le butanol.

5. La composition de la revendication 1, dans laquelle l'alcool gras est choisi parmi l'alcool cétylique, l'alcool stéarylique, l'alcool laurylique, l'alcool myristylique et l'alcool palmitylique.

6. La composition de la revendication 1, dans laquelle l'agent tensio-actif éthoxylé est choisi parmi le stéarate, le palmitate ou l'oléate de sorbitan éthoxylé, les éthoxylats de nonylphénol et les éthoxylats d'alcool gras.

7. La composition de la revendication 1, dans laquelle le propulseur est choisi parmi le propane, le butane, le dichlorodifluorométhane, le dichlorotétrafluoroéhane et l'octafluorocyclobutane.

8. Une composition selon la revendication 2, dans laquelle l'inhibiteur de la corrosion est présent en des proportions de 0,1 à 15 % p/p.

9. La composition de la revendication 2, dans laquelle le sel d'acide organique est choisi parmi ceux de l'acide sorbique et de l'acide benzoïque.

10. La composition de la revendication 1 comprenant de plus un émollient.

11. La composition de la revendication 11, dans laquelle l'émollient est choisi parmi la lanoline, l'alcool vinylique, la polyvinylpyrrolidone et les polyols choisis dans le groupe du glycérol, du propylèneglycol et du sorbitol.

Patentansprüche

1. Biozide Zusammensetzung, mit:
   (a) 0,1 bis 10 Gew.-% Chlorhexidin;
   (b) 40 bis 90 Gew.-% aliphatischem Alkohol;
   (c) bis zu 40 Gew.-% Wasser;
   (d) 0,5 bis 10 Gew.-% Fettalkohol;
   (e) 0,1 bis 15 Gew.-% oberflächenaktivem Mittel;
   (f) 3 bis 30 Gew.-% Treibmittel.

2. Zusammensetzung nach Anspruch 1, weiter gekennzeichnet durch einen Gehalt an einem Korrosionsinhibitor auf der Basis eines Salzes einer organischen Säure.

3. Zusammensetzung nach Anspruch 1, dadurch gekennzeichnet, daß das Chlorhexidin ausgewählt ist aus einem Glukonat, Acetat oder Hydrochlorid.

4. Zusammensetzung nach Anspruch 1, dadurch gekennzeichnet, daß der aliphatische Alkohol ausgewählt ist aus Methanol, Ethanol, Isopropanol und Butanol.

5. Zusammensetzung nach Anspruch 1, dadurch gekennzeichnet, daß der Fettalkohol ausgewählt ist aus Cetylalkohol, Stearylalkohol, Laurylalkohol, Myristylalkohol und Palmitylalkohol.

6. Zusammensetzung nach Anspruch 1, dadurch gekennzeichnet, daß das ethoxylierte oberflächenaktive Mittel ausgewählt ist aus ethoxyliertem Sorbitanstearat, -palmitat, -oleat, Nonylphenolethoxylaten und Fettalkoholethoxylaten.

7. Zusammensetzung nach Anspruch 1, dadurch gekennzeichnet, daß das Treibmittel ausgewählt ist aus Propan, Butan, Dichlordifluormethan, Dichlortetrafluorethan und Octafluorcyclobutan.

8. Zusammensetzung nach Anspruch 2, dadurch gekennzeichnet, daß der Korrosionsinhibitor in Mengen von 0,1 bis 15 Gew.-% vorliegt.

9. Zusammensetzung nach Anspruch 1, dadurch gekennzeichnet, daß das Salz der organischen Säure ausgewählt ist aus Sorbinsäure und Benzoesäure.

10. Zusammensetzung nach Anspruch 1, weiter gekennzeichnet durch ein erweichendes Mittel.

11. Zusammensetzung nach Anspruch 10, dadurch gekennzeichnet, daß das erweichende Mittel ausgewählt ist aus Lanolin, Vinylalkohol, Polyvinylpyrrolidon und Polyolen, ausgewählt aus der Gruppe, die aus Glycerin, Propylenglycol und Sorbit besteht.